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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/811,998

03/30/2004

Ruey J. Yu

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EXAMINER

SCHLIENTZ, NATHAN W

ART UNIT

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1616

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/811,998	Applicant(s) YU ET AL.	
	Examiner Nathan W. Schlientz	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 111-162 is/are pending in the application.
- 4a) Of the above claim(s) 122-148, 152-158 and 162 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 111-121, 149-151 and 159-161 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>3/30/04 and 8/01/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, claims 111-121, 149-151 and 159-161, in the reply filed on 21 June 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Applicant's election of the species retinoic acid, ammonium hydroxide, N-methylglucamine, and arginine is acknowledged.

Status of Claims

Claims 111-162 are pending. However, claims 122-148, 152-158 and 162 are withdrawn from further consideration as being drawn to a non-elected invention. Therefore, claims 111-121, 149-151 and 159-161 are examined herein on the merits for patentability. No claim is allowed at this time.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

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1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 149-150, 153 and 159 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 3 of U.S. Patent No. 5,561,157. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to a composition comprising lactobionic acid. Therefore, the scope of the copending applications is overlapping, and thus they are obvious variants of one another.

2. Claims 149-150 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 15, 23, 27-29 and 32-35 of U.S. Patent No. 5,877,212. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to a composition comprising lactobionic acid and organic alkali, such as glycineamide, arginineamide, prolineamide, lysineamide, glucamine, and aminoinositols. Therefore, the scope of the copending applications is overlapping, and thus they are obvious variants of one another.

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3. Claims 149-150 and 152-153 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 8 and 14 of U.S. Patent No. 5,942,250. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to a composition comprising lactobionic acid. Therefore, the scope of the copending applications is overlapping, and thus they are obvious variants of one another.

4. Claims 111-121, 149-151 and 159-161 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7, 20-26, 29-30, 43-49, 52-56 of U.S. Patent No. 6,335,023. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to a composition comprising a therapeutically effective amount of at least one aldobionic acid, as listed in claim 111 of the instant application, a topically active agent, as listed in claim 115 of the instant application, and an inorganic or organic alkali or amphoteric substance, as listed in claims 117-121 of the instant application. Therefore, the scope of the copending applications is overlapping, and thus they are obvious variants of one another.

5. Claims 111-121, 149-151 and 159-161 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10, 32-34, 36-41 and 46-48 of U.S. Patent No. 6,740,327. Although the conflicting claims are not identical, they are not patentably distinct from each other because both

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sets of claims are directed to a composition comprising a therapeutically effective amount of at least one aldobionic acid, as listed in claim 111 of the instant application, a topically active agent, as listed in claim 115 of the instant application, and an inorganic or organic alkali or amphoteric substance, as listed in claims 117-121 of the instant application. Therefore, the scope of the copending applications is overlapping, and thus they are obvious variants of one another.

6. Claims 111-115, 149-154 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 21-22, 29 and 35-36 of copending Application No. 10/792,273. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to a composition comprising lactobionic acid, isolactobionic acid, maltobionic acid, cellobionic acid, gentiobionic acid, kojibionic acid, malibionic acid, nigerobionic acid, rutinobionic acid, and sophorobionic acid. Therefore, the scope of the copending applications is overlapping, and thus they are obvious variants of one another.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. Claims 111-115, 149-154 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 21-22 and 29 of copending Application No. 11/050,434. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims

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are drawn to a composition comprising lactobionic acid, isolactobionic acid, maltobionic acid, cellobionic acid, gentiobionic acid, kojibionic acid, malibionic acid, nigerobionic acid, rutinobionic acid, and sophorobionic acid. Therefore, the scope of the copending applications is overlapping, and thus they are obvious variants of one another.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. Claims 111-112, 149-154 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 21-22 of copending Application No. 11/320,530. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to a composition comprising lactobionic acid or maltobionic acid. Therefore, the scope of the copending applications is overlapping, and thus they are obvious variants of one another.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Claims 111-115, 149-154 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 22 and 24 of copending Application No. 11/621,287. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to a composition comprising lactobionic acid or maltobionic acid. Therefore, the scope

of the copending applications is overlapping, and thus they are obvious variants of one another.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 149-150 and 152-153 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 4,895,716 (hereinafter Goldstein et al.).

Goldstein et al. disclose a composition comprising from about 0.05 to 0.5% w/v lactobionic acid and from about 0.2 to 5.0% w/v glycine (claims 1 and 7). It is noted that Goldstein et al. do not disclose the composition as an antioxidant composition. However, the composition of Goldstein et al. comprises the same ingredients as the composition of the instant claims. Therefore, the composition of Goldstein et al. will inherently possess antioxidant properties.

The examiner respectfully points out the following from MPEP 2112: "The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). In *In re Crish*, 393 F.3d 1253, 1258, 73 USPQ2d 1364, 1368 (Fed. Cir. 2004), the court stated that "just as the discovery of properties of a known material does not make it novel, the identification and characterization of a prior art material also does not make it novel."

2. Claims 149-150 and 152-153 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,405,641 (hereinafter Kurihara et al.).

Kurihara et al. disclose a taste-modification composition comprising one part by weight or more salt selected from sodium phosphate, sodium carbonate and sodium acetate; and one part by weight or more total parts by weight of an organic acid selected from lactobionic acid (claims 1, 4 and 6-8). It is noted that Kurihara et al. do not disclose the composition as an antioxidant composition. However, the composition of Kurihara et al. comprises the same ingredients as the composition of the instant claims. Therefore, the composition of Kurihara et al. will inherently possess antioxidant properties.

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3. Claims 149-150 and 152-153 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,561,157 (hereinafter Yu '157).

Yu '157 disclose a topically effective skin treating composition comprising lactobionic acid (claims 1 and 3).

4. Claims 111-115, 149-154 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,703,160 (hereinafter Dehennau et al.).

Dehennau et al. disclose a biodegradable composition comprising 1-10 wt.% of at least one salt of an hydroxycarboxylic acid, such as maltobionic acid and lactobionic acid, and at least one adjuvant selected from the group consisting of urea and hydrogenated sugars (claims 1, 15, 19-20, 23, 30, 41-42).

5. Claims 149-150 and 152-153 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 5,977,127 (hereinafter Bonnacker et al.).

Bonnacker et al. disclose a solid pharmaceutical preparation comprising up to 50 wt.% of a water-soluble acid additive comprising lactobionic acid (claims 1 and 13). It is noted that Bonnacker et al. do not disclose the preparation as an antioxidant composition. However, the composition of Bonnacker et al. comprises the same ingredients as the composition of the instant claims. Therefore, the composition of Bonnacker et al. will inherently possess antioxidant properties.

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6. Claims 111-112, 116 and 118-119 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication 2003/0010254 (hereinafter Mentink et al.).

Mentink et al. disclose a composition comprising lactobionic acid or maltobionic acid, and ethanolamine (claims 1, 4 and 5). It is noted that Mentink et al. do not disclose a therapeutically effective amount of lactobionic acid or maltobionic acid. However, the instant specification does not define a therapeutically effective amount, but provides examples wherein an effective amount was used. In particular, Example 5, composition (c) discloses 0.5% lactobionic acid as a suitable amount for topical use on hair, scalp, nail or skin, or use for wound healing or general care of oral or vaginal mucosa (page 36, lines 9-11 and 20-22). Mentink et al. disclose the oxidized sugar (i.e. lactobionic acid and maltobionic acid) is present in 1-99%, preferably 3-75%, more preferably 5-60% (paragraphs [0023] and [0031]; and claims 1-3). Therefore, Mentink et al. fully anticipate all the limitations of the instant claims.

Contact Information

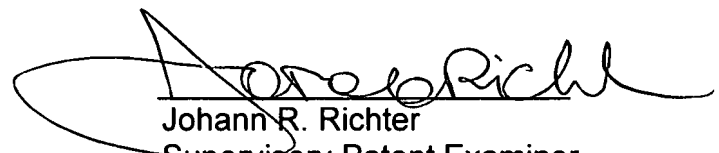
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan W. Schlientz whose telephone number is 571-272-9924. The examiner can normally be reached on 8:30 AM to 5:00 PM, Monday through Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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